SRKW
SPECTOR ROSEMAN
KODROFF & WILLIS PC

Direct Email:
jmacoretta@srkw-law.com

December 9, 2014

Via ECF and Facsimile (267) 299-5060

The Hon. Lynne A. Sitarski
United States District Court
Eastern District of Pennsylvania
601 Market Street, Room 3015
Philadelphia, PA 19106

Re: *United States ex rel. Krahling v. Merck & Co., Inc.*, Civ. Action No. 10-4374 & *In re: Merck Mumps Vaccine Antitrust Litigation*, Master File No. 12-3555

Dear Judge Sitarski:

Relators and Private Plaintiffs in the above-listed actions (together, "the Actions") move the Court to (i) enter their jointly proposed Protective Order[1] as the operative Protective Order in the Actions and (ii) enter an order compelling Defendant Merck & Co., Inc. ("Merck") to produce the documents it previously produced to the Department of Justice ("DOJ") concerning the exact same subject matter as that of the Actions.[2]

This litigation began in August 2010 when Relators Stephen A. Krahling and Joan A. Wlochowski, both of whom previously worked in Merck's vaccines division, filed an action under the False Claims Act alleging (i) Merck's ongoing failure to disclose and efforts to conceal in violation of its multiple duties to the

[1] *See* Relators' and Private Plaintiffs' Proposed Protective Order, attached as Exhibit A.
[2] Relators and Private Plaintiffs drafted a joint letter in the interest of efficiency. Counsel for Private Plaintiffs sign the letter with the consent of counsel for Relators.

government the significantly diminished efficacy of its Mumps Vaccine,[3] and (ii) Merck's continued sale to the government of a vaccine that it falsely represents as having an efficacy rate significantly higher than it actually is. Private Plaintiffs filed their action in June 2012 based on the same underlying conduct. They allege that Merck's conduct violates the Sherman Antitrust Act, in that Merck intended to and has foreclosed competition in the mumps vaccine market, and that Merck's conduct also violates the Consumer Protection Laws of New Jersey, New York and California.

The discovery schedule agreed to by Merck and ordered by the Court requires substantial completion of all document discovery by February 27, 2015, less than 90 days from now.[4] Counsel for Relators and Private Plaintiffs have engaged in many good-faith efforts to resolve these discovery disputes, but now believe that, without court intervention, Merck will continue to delay Relators' and Private Plaintiffs' efforts to move discovery forward and meet the Court-ordered discovery schedule.

I. Motion To Enter Jointly Proposed Protective Order

Despite nearly five weeks of negotiations, the Parties have been unable to reach an agreement on a Stipulated Protective Order. While the Parties have successfully narrowed the issues in dispute, a final agreement could not be reached on three discrete issues.

First, Merck seeks to prohibit Relators and Private Plaintiffs from seeing a broad category of documents Merck wants to label as "HIGHLY CONFIDENTIAL – ATTORNEYS' EYES ONLY" ("AEO").[5]

Merck has not offered any justification for this proposed ban other than the unfounded assertion that Relators and Private Plaintiffs – despite being the Parties that brought these actions – simply do not need to view AEO information. Merck also has failed to explain how disclosure to Relators and Private Plaintiffs –

---

[3] Mumps Vaccine, as used herein, includes any vaccine Merck sold or sells designed to inoculate or otherwise protect the vaccine recipient from contracting mumps and includes MMR®, M-M-R®II and ProQuad®.

[4] *See* Order, 12-cv-03555, Nov. 14, 2014, ECF No. 70.

[5] *See* Comparison of Relators' and Private Plaintiffs' Proposed Protective Order to Merck's Proposed Protective Order at § 2.9, attached as Exhibit B.

none of whom are competitors of Merck and all of whom will have agreed to be bound by the terms of the Protective Order ultimately entered in the Actions – could cause Merck any harm.[6] As such, Merck has not met its burden to demonstrate "good cause" exists for each AEO designation. *Pansy v. Borough of Stroudsburg*, 23 F.3d 772, 786 (3d Cir. 1994). Under Third Circuit precedent "[b]road allegations of harm, unsubstantiated by specific examples or articulated reasoning, do not support a good cause showing." *Id.* (internal quotation marks and citation omitted); *see also Yansick v. Temple Univ. Health Sys.*, 297 F. App'x 111, 115 (3d Cir. 2008) ("[V]ague and speculative allegations . . . are insufficient to demonstrate the requisite injury and otherwise fail to show that the balance of relevant interests weigh in favor of confidentiality."). During the Parties' negotiations, Merck has repeatedly been unable to give a single specific example of a document that, if shown to Relators and/or Private Plaintiffs, would cause such harm as to necessitate the AEO designation.

Instead, it is Relators and Private Plaintiffs who will be prejudiced if denied access to relevant material simply because Merck unilaterally designates it off-limits. As just one example, Merck seeks to bar Relators from seeing "documents reflecting the manufacturing process for Merck's Mumps Vaccine,"[7] even where such documents relate to the efficacy, potency, or proper labeling of Merck's Mumps Vaccine. Yet Relators' experience as former virologists at Merck will be critical to assist their attorneys in understanding these documents. As another example, the Private Plaintiffs will need access to "pricing and cost information" – information designated by Merck as AEO – to accurately assess and calculate their damages.[8]

Moreover, Merck's designation of its meager production to date – incomplete organizational charts – as Confidential shows a predisposition to overdesignate when it comes to confidentiality concerns (real or devised).[9] Merck has not offered any explanation as to why these organizational charts and basic

---

[6] According to Exhibit B at § 2.9, the designation is necessary to prevent disclosure of extremely sensitive material that could cause Merck a "competitive disadvantage" or "substantial risk of serious harm".

[7] *See* Exhibit B at § 2.9(c).

[8] *See* Exhibit B at § 2.9(d).

[9] *See, e.g.*, MRK-KRA0000008/MRK-CHA0000008-24, attached as Exhibit C. Since Merck called these documents "Confidential" they must be filed with the Court under seal.

information concerning relevant individuals, such as title and division within Merck, should be confidential. Some of it is even publicly available.

Additionally, Merck goes even further and redacts information that is in no way confidential – such as an employee's office location and the identity of an employee's assistant – and is entirely relevant to the ability of Relators and Private Plaintiffs to assess whether Merck has named the appropriate document custodians. As even Merck has proposed, material should only be designated Confidential if it contains "confidential and non-public development, financial or commercial information or non-public personal information".[10] Merck's interpretation of the designation Confidential thus far reinforces the likelihood of significant prejudice to Relators and Private Plaintiffs if Merck is permitted to prohibit them from reviewing what will inevitably be the substantial swathe of documents Merck designates as AEO.

Second, Merck also seeks to bar Relators and Private Plaintiffs from showing their potential experts any documents Merck designates as Confidential or AEO without first getting Merck's approval. Merck might have a legitimate concern with respect to experts currently working on a mumps vaccine for a competing pharmaceutical company. And Relators and Private Plaintiffs agreed to this restriction for this class of potential experts. But Merck insists on going significantly further to include any potential expert who is currently an employee, consultant or contractor for any pharmaceutical company, research organization or university that manufactures, sells, developed or is developing a mumps vaccine ***regardless of whether the individual was ever involved***.[11] In other words, if Relators or Private Plaintiffs retain an expert or consultant who works for an entity which ***at any time*** developed a mumps vaccine, regardless of the expert's involvement in or knowledge of the work (or whether he or she was even there at the time), Relators and Private Plaintiffs would have to disclose the expert's identity to Merck and get Merck's permission before even showing him or her virtually any document Merck ultimately produces in this case. And if Merck refuses, Relators and Private Plaintiffs will either have to find a different expert or consultant, or seek the Court's intervention.

---

[10] *See* Exhibit B at § 2.2.
[11] *See* Exhibit B at §§ 2.6, 7.2(e), 7.3(f) and 7.4(b).

Third, Merck seeks to bar Relators and Private Plaintiffs from showing materials designated AEO to ***any*** government employees other than DOJ attorneys.[12] This would preclude Relators and Private Plaintiffs from showing these documents at depositions or otherwise to any employees of the Food and Drug Administration, Centers for Disease Control, National Institutes for Health, National Vaccine Program or the Health and Human Services Department. These are the very government agencies tasked with overseeing the country's vaccine program and with which Merck routinely has to deal in the development, licensing, labeling, manufacture and sale of its mumps vaccine. Merck has offered no legitimate reason for prohibiting Relators or Private Plaintiffs from showing these documents to these agencies and has identified no harm it will suffer from any such disclosure.[13]

Despite the Parties' efforts to resolve these three issues, they have reached impasse.[14] Relators and Private Plaintiffs therefore respectfully ask this Court to enter their jointly proposed Protective Order as the operative Protective Order in the Actions.[15]

II. Motion To Compel DOJ Documents

After Relators filed their original complaint, the DOJ began an investigation and sought documents from Merck concerning the allegations in these Actions, which Merck then produced to the DOJ (the "DOJ Documents"). Relators and Private Plaintiffs have been trying to obtain these documents from Merck for almost two months.[16] Merck responded by raising various objections, but agreed to produce the DOJ Documents subject to the entry of a "mutually agreeable

---

[12] *See* Exhibit B at § 7.3(d).

[13] A minor dispute between the Parties also exists with respect to whether current employees who are deposed and who are bound by the Protective Order ultimately entered in the Actions may retain the transcript of their testimony if the deposition contains Confidential or AEO material. *See* Exhibit B at § 7.3(i).

[14] The Parties met and conferred on November 24, 2014 and December 1, 2014 and also corresponded extensively regarding the terms of a Stipulated Protective Order.

[15] *See* Exhibit A.

[16] *See* Private Plaintiffs' First Request for Production of Documents (dated October 17, 2014) and Relators' First Set of Document Requests (dated October 23, 2014), Request No. 1, attached as Exhibits D and E, respectively.

protective order".[17] Unfortunately, as detailed above, the Parties have been unable to reach an agreement on a Stipulated Protective Order.

In an attempt to move discovery forward, Relators and Private Plaintiffs have asked Merck to produce the DOJ Documents now, subject to their provisional agreement not to show the documents to anyone except counsel for Relators and Private Plaintiffs and their staffs.[18] Despite this agreement to restrict access to their counsel and staff, Merck still refuses to produce the DOJ Documents. Merck has offered no explanation for its continued refusal.[19] It has none. Merck has already gathered, reviewed and produced the DOJ Documents. Thus there should be no delay or burden in making an identical production to counsel in the Actions. In fact, for this reason, courts in this District regularly grant such requests.[20]

There are substantial reasons to compel Merck to produce the DOJ Documents now. Presumably the DOJ Documents are highly relevant to the claims in the Actions. If counsel for Relators and Private Plaintiffs can promptly review the DOJ Documents, it may help streamline discovery by assisting in the crafting of future discovery requests and negotiating electronic search queries and the list of relevant document custodians.

Relators and Private Plaintiffs therefore respectfully ask this Court to enter an Order requiring Merck to produce the DOJ Documents within three business days.[21]

---

[17] *See* Merck's Responses and Objections to Plaintiffs' First Request for Production of Documents and Merck's Responses and Objections to Relators' First Set of Document Requests, attached as Exhibits F and G, respectively.

[18] The production would remain AEO until the Court enters a Protective Order in the Actions, at which time the DOJ Documents would be subject to the terms and designations of the Order.

[19] Plaintiffs' counsel and Merck's counsel have discussed this issue several times, both by telephone and email, and have been unable to resolve their dispute.

[20] *See, e.g., Golden Quality Ice Cream Co. v. Deerfield Specialty Papers, Inc.*, 87 F.R.D. 53, 59 (E.D. Pa. 1980) (granting plaintiffs' request for documents in defendants' possession that were turned over to the grand jury because "the documents in question have already been identified and sorted, compliance with this request should impose only a minimal burden upon the defendants."); *see also In re Plastics Additives Antitrust Litig.*, No. 03-2038, 2004 U.S. Dist. LEXIS 23989, at *38-39 (E.D. Pa. Nov. 30, 2004) (noting defendants in antitrust litigation "regularly agree through joint discovery schedules to produce documents submitted to the DOJ . . . concerning the basis for the antitrust civil suit" and finding "[t]his willingness to produce such documents at the outset of litigation signals the appropriateness and relevance of such a discovery request" and thus requiring defendants produce all documents produced to the DOJ).

[21] *See* Proposed Order, attached as Exhibit H.

We are, of course, available to discuss this further, or provide any supplemental briefing requested by the Court.

Respectfully submitted,

John A. Macoretta
Partner

JAM:jam
Attachments
cc: All Counsel of Record in the Actions (*via* ECF and E-mail)